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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,832	07/10/2000	SUZANNE CORY	017227/0159	3471

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EXAMINER	
YU, MISOOK	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,832	CORY ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9,15-21,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *6,15 and 19* is/are allowed.

6)☒ Claim(s) *7,16,17,20,29 and 30* is/are rejected.

7)☒ Claim(s) *8, 9, and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/20/00*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/06/2004 has been entered.

This Office action contains new grounds of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 6-9, 15-21, 29, and 30, are pending. Applicant's request to rejoin (under the TCT' standard of unity of invention) the pending claims drawn to the polypeptide encoded by the previously examined nucleic acid molecule is granted.

Claims 6-9, 15-21, 29, and 30 are examined on merits.

Priority

The two foreign priority documents, i.e. PO 9263, and PO 9373 have been received.

Information Disclosure Statement

A copy of 1449 filed on 07/20/2000 is attached with this Office action as per applicant's request.

Claim Objections

Claims 16, 21, 29, and 30 are under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The scope of the claims is broader than the scope of the base claims. In claim 16, not all of the nucleotide sequence capable of hybridizing to SEQID NO:9 under moderate stringency conditions have at lest 89% identity to SEQ ID NO:9.

The structure of the claimed nucleic acid in instant claim 21 and claimed polypeptides in claims 29, and 30 are different from the structure of claimed nucleic acid in claims 6 and 15, respectively. Claims 21, and 29 as currently construed say that what is being claimed is a "variant", which is outside the scope of the property boundary set by claim 6, and 15. The structure of claims 6, and 15 is used as a reference point to describe the claimed variant, the limitation of claims 6, and 15 are not included in claims 21, and 29. Claims 21, and 29, and 30 do not set the maximum number of amino acid modification away the reference point. If all the species of the dependent claims do not belong the genus in the base claims, then the dependent claims do not further limit.

Applicant argues that the variant in claim 21 is only to the extent of having 89% or greater identity to SEQ ID NO:10. The argument has been fully considered but found unpersuasive because the claims are not drafted as applicant argues. See the claim interpretation above. If the scope of the claimed variant is such that claimed product has 89% or sequence identity to SEQ ID NO:10, then the claims should be drafted as such.

Claim Rejections - 35 USC § 112

Claim 7 **remain rejected** and claims 16, and 17 are **newly rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Any other previous rejection not repeated is withdrawn in view of amendment.

Claims 7, and 16 recite "under moderate stringency conditions" but it is not clear what the metes and bounds are for the term. The term " under moderate stringency conditions" is not defined by the claim or the specification. What will hybridize depends on the conditions but the paragraph bridging pages 21 and 22 of the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant argues that the low stringency condition is defined in the specification, and with this description in mind, one of skill in the art would be reasonably apprised of the scope of moderate stringency conditions. This argument has been fully considered but found unpersuasive because the claims do not recite the low stringency condition defined in the specification.

Claim 17 recites "further comprising" and it is not clear whether the limitation makes the claimed isolated polypeptide to have at least one tandem repeat of SEQ ID NO:10 or sequence having at least about 89% identity to SEQ ID NO:10 that is already present in the base claims.

The rejection of claim 9 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment.

The rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description requirement is withdrawn** either in view of the amendment or on reconsideration, there are so many proteins that induce apoptosis if most of the protein sequence of instant SEQ ID NO:10 is changed (for claims 7, 21, 29, 30, see also for the art rejection below).

The rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view that the art knows many protein sequences that induce apoptosis (see the art rejection below).

Claim 20 is newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claim 20 is drawn to SEQ ID NO:10, or proteins having at least 89% or greater identity to SEQ ID NO:10 in homodimeric form.

The specification at page 63, and 74 teach that SEQ ID NO:9 protein binds to Bcl-2 and dynein. However, the specification does not teach whether any of the claimed protein forms homodimeric form. Connor et al., of record (The EMBO Journal Vol.17 No.2 pp.384-395, 1998) at page 389 (Fig. 6) teach that whether something forms a dimer or require screening. The specification does not teach how to make the claimed protein that forms homodimer.

Considering the unpredictable state of art, limited guidance, and no examples in the specification how to make the instantly claimed invention, it is concluded that undue experimentation is required to practice the invention. It is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves.

Claim Rejections - 35 USC § 102

Claims 7, 16, 21, 29, and 30 are under 35 U.S.C. 102(b) as being anticipated by Oltvai et al., of record (27 August 1993, Cell 74, 609-619). Claims 7, 29, and 30 are newly rejected with this Office action.

Claims 7, 16, 21, 29, and 30 are broadly interpreted as drawn to an apoptosis inducing protein encoding isolated nucleic acid molecule hybridizes to SEQ ID NO:9 under undefined conditions, i.e. "moderate stringency conditions" (claims 7, 16), a variant of said nucleic acid (claim 21), or any variant of SEQ ID NO:10 (claims 29, and

30), wherein the claimed products is either encodes the protein or protein that induces apoptosis. Claims 21, and 29 are drawn to a "variant of an isolated nucleic acid molecule as claimed in claim 6" or a "variant of an isolated polypeptide as claimed in claim 15" respectively. The structure of the claimed nucleic acid in instant claim 21 and claimed polypeptide are different from the structure of claimed nucleic acid in claims 6 and 15, respectively. Claims 21, and 29 as currently construed say that what is being claimed are a "variant", which is outside the scope of the property boundary set by claim 6, and 15. Claims 6, and 15 are used as a reference point to describe the claimed variant, the limitation of claims 6, and 15 are not included in claims 21, and 29. Claims 21, and 29, and 30 do not set the maximum number of amino acid modification away the reference point.

Oltvai et al., in Figure 2 (page 611) teaches a cDNA sequence which encode Bax beta capable of inducing apoptosis (note Fig. 7 for apoptosis assay) and also teaches an isolated DNA molecule that encodes LRRIGDE (amino acids #64-70 of Bax), which is identical to LRRIGDE, amino acids #148-154 of instant SEQ ID NO:10. In other words, Oltvai et al., teach at least 21 contiguous nucleotides that either directly match or degenerate codons of LRRIGDE. It is the Office's position that this sequence would hybridizes to the instant SEQ ID NO:9. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the nucleic acid of the prior art does not hybridizes to the instant SEQ ID NO:9 under the unspecified condition. In the absence of evidence to the contrary, the burden is on the

applicant to prove that the nucleic acid of Oltvai et al., is incapable of hybridizing to instant SEQ ID NO:9 "under moderate stringency conditions".

As for the variant of claim 21, 29, and 30, the claims do not define the structure. As stated above, only the reference structure, i.e. the structure claimed in claims 6, 15 respectively. The limitation "which amino acid addition, substitution and/or deletion is in the region defined by amino acid residue numbers 42-131" is interpreted as saying that at least one mutation occurs in the region. Since the claims do not say the maximum number of amino acids being mutated, the instantly claimed variants read on the protein shown at Fig. 2 encoded by the cDNA of Bax, and the many different Baxs and Bcl-2s as shown at Fig. 6 of Oltvai et al. The proteins of prior art induce apoptosis. As for the limitation that the claimed variant does not associate a dynein light chain, it is the Office's position that the variant of the prior art inherently does not have the function.

Applicant argues that claim 21 depends from a base claim, and the rejection is improper. This argument has been fully considered but found unpersuasive for reasons given above for the interpretation of the scope encompassed by the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

MISOOK YU
PATENT EXAMINER